

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE AG, ALCON, INC.	)	
and ALCON MANUFACTURING, LTD.,	)	
	)	
Plaintiffs,	)	
	)	
	)	
v.	)	Civil Action No. 06-234 (SLR)
	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Defendant.	)	
_____	)	

**STIPULATED PROTECTIVE ORDER**

Whereas pretrial discovery in this action may necessarily involve the disclosure of trade secrets or confidential research, development, or commercial information of one or more parties and of non-parties from whom such discovery may be sought; and

Whereas the parties have in good faith conferred and have agreed upon the terms of a Protective Order and for good cause shown; therefore

The parties stipulate, pursuant to Rule 26(c) of the Federal Rules of Civil Procedure, subject to the approval of the Court, to the following Protective Order:

**1. Scope of Protection.**

1.1 This Protective Order shall govern any record of information, designated pursuant to ¶ 2 of this Protective Order, produced in this action, including all designated deposition testimony, all designated testimony taken at a hearing or other proceeding, all designated interrogatory answers, documents and other discovery materials, whether produced informally or in response to interrogatories, requests for admissions, requests for production of documents or other formal method of discovery.

1.2 This Protective Order shall also govern any designated record of information produced in this action pursuant to required disclosures under any federal procedural rule or District of Delaware local rule, and any supplementary disclosures thereto.

1.3 This Protective Order shall apply to the parties and any nonparty from whom discovery may be sought and who desires the protection of this Protective Order.

**2. Designation.**

2.1 Each party shall have the right to designate as confidential and subject to this Protective Order any information produced in this action which contains, reflects, or otherwise discloses confidential technical, business or financial information (“CONFIDENTIAL” information). To the extent that material is marked CONFIDENTIAL, such material shall only be revealed to or used by limited categories of individuals, as provided for in ¶ 4.1, and shall not be communicated in any manner, either directly or indirectly, to any person or entity not permitted disclosure pursuant to this Protective Order. Any copies of such material, abstracts, summaries or information derived therefrom, and any notes or other records regarding the contents thereof, shall also be deemed CONFIDENTIAL, and the same terms regarding confidentiality of these materials shall apply as apply to the originals.

2.2 Each party shall have the right to designate as highly confidential and subject to this Protective Order any information produced in this action which contains, reflects, or otherwise discloses proprietary manufacturing information, trade secrets, research and development information or competitively sensitive commercial or financial information, (“HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY” information). To the extent that material is marked HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY, such material shall be revealed to or used by limited categories of individuals, as

provided for in ¶ 4.2, and shall not be communicated in any manner, either directly or indirectly, to any person or entity not permitted disclosure pursuant to this Protective Order. Any copies of such material, abstracts, summaries or information derived therefrom, and any notes or other records regarding the contents thereof, shall also be deemed HIGHLY CONFIDENTIAL - OUTSIDE ATTORNEYS' EYES ONLY, and the same terms regarding confidentiality of these materials shall apply as apply to the originals.

2.3 To the extent that any party has, prior to the date that this Order is entered, produced to the other side materials that the producing party has marked with any confidentiality designation, all such materials shall be considered to have been designated under this Order as HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY unless otherwise agreed by the Parties.

### **3. Limit On Use And Disclosure Of Designated Information.**

3.1 Each party and all persons bound by the terms of this Protective Order shall use any information or document designated CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY only in connection with the prosecution or defense of this action, except by consent of the parties or order of the Court. Except as provided for in this Order, no party or other person shall disclose or release any information or document governed by this Protective Order to any person not authorized pursuant to this Protective Order to receive such information or document.

3.2 It is, however, understood that counsel for a party may give advice and opinions to his or her client based on his or her evaluation of designated CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY information received by the party, provided that such rendering of advice and opinions shall not reveal the content of such information, other than in summary form, except by prior written agreement with counsel for the producing party.

3.3 The attorneys of record for the parties and other persons receiving information governed by this Protective Order shall exercise reasonable care to insure that the information and documents governed by this Protective Order are (a) used only for the purposes specified herein, and (b) disclosed only to authorized persons.

**4. Disclosure Of Confidential Material.**

4.1 Except as provided in ¶¶ 10, 12, and 17, documents or information designated CONFIDENTIAL shall be disclosed by the recipient thereof, on a need-to-know basis, only to:

(a) No more than three designated in-house attorneys or patent agents and their authorized secretarial, paralegal, clerical and legal assistant staff. For Bayer, the designated persons shall be Georg Kirsch, Stefan Beyreuther, and Barbara Shimei. For Alcon, the designated persons shall be Barry Copeland, John Reding, and Patrick Ryan. For Teva, the designated persons shall be Richard S. Egosi, David M. Stark, and James E. Bauersmith.. In the event that one of the aforementioned individuals ceases to have responsibilities relating to this litigation, a party may designate another in-house attorney or patent agent to replace such person upon giving written notice of such change to the opposing party or parties.

(b) outside trial counsel or outside attorneys of record for the parties, including such attorneys' partners, associates, staff and contract attorneys, and their authorized secretarial, paralegal, clerical and legal assistant staff;

(c) the Court and Court personnel, as provided in ¶ 11;

(d) consultants or experts and their staffs retained by the parties or their attorneys for purposes of this action, who are not objected to pursuant to ¶ 5, who are not employees or otherwise affiliated with either of the parties, and who first agree to be bound by the terms of this Protective Order;

(e) court reporters, videographers, and their respective staffs employed in connection with this action; and

(f) non-parties specifically retained to assist outside counsel of record with copying and computer services necessary for document handling, and other litigation support personnel (e.g., graphic designers and animators, database entry personnel).

4.2 Except as provided in ¶¶ 10, 12, and 17, documents or information designated HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY shall be disclosed by the recipient thereof, on a need-to-know basis, to those categories of individuals listed in ¶¶ 4.1 (b)-(f).

## **5. Identification Of Experts.**

5.1 If any party desires to disclose information designated CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY to any expert or consultant pursuant to ¶ 4.1(d) above, it must first identify in writing (which can be by facsimile) to the attorneys for the producing party each such expert or consultant. The attorney for the producing party shall have five (5) business days from receipt of such notice to object to disclosure of such information to any of the experts or consultants so identified. Any party that fails to object within 5 business days of receiving such notice shall be deemed to have waived such objection and the parties shall be deemed to have agreed upon disclosure to the expert for purposes of ¶ 4.1(c). No CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY information may be disclosed to any proposed expert or consultant until such time as the parties are deemed to have agreed upon disclosure to the expert for purposes of ¶ 4.1(d) pursuant to the provisions of ¶¶ 5.1 or 5.2.

5.2 The identification of an expert or consultant pursuant to ¶ 5.1 shall include the full name and professional address and/or affiliation of the proposed expert or consultant, an up-to-date curriculum vitae, any prior or current employments or consultancies for any party or other company in the pharmaceutical industry within the last ten years, including a list of the cases in

which the expert or consultant has testified at deposition, at a hearing, or at trial within the last four years. The parties shall attempt to resolve any objections informally. If the objections cannot be resolved, the party opposing disclosure of the CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY information to the expert or consultant may move the Court for an Order prohibiting the disclosure or otherwise raise the issue with the Court. If a motion is filed, the party opposing disclosure shall bear the burden of proof with respect to the propriety of its objection and blocking of said individual from serving as an expert or consultant in this case. Any party that fails to file such a motion or otherwise raise such an issue with the Court within 10 business days of notifying a party of an objection to disclosure under ¶ 5.1 shall be deemed to have waived such objection and the parties shall be deemed to have agreed upon disclosure to the expert for purposes of ¶ 4.1(d).

**6. Agreement Of Confidentiality.**

In no event shall any information designated CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY be disclosed to any person authorized pursuant to ¶¶ 4.1 (d) until such person has executed a written Confidentiality Undertaking (in the form set forth in Exhibit A hereto) acknowledging and agreeing to be bound by the terms of this Protective Order. Counsel for the party seeking to disclose material designated under this Order to any such person pursuant to this paragraph shall be responsible for retaining the executed originals of all such Confidentiality Undertakings.

**7. Related Documents.**

The restrictions contained herein to the use of information designated CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY shall apply to (a) portions of documents, copies, extracts, and complete or partial summaries prepared from or

containing such information; (b) portions of deposition transcripts and exhibits thereto which contain or reflect the content of any such documents, copies, extracts, or summaries; (c) portions of briefs, memoranda or any other papers filed with the Court and exhibits thereto which contain or reflect the content of any such documents, copies, extracts, or summaries; (d) deposition testimony designated in accordance with ¶ 8; and/or (e) testimony taken at a hearing or other proceeding that is designated in accordance with ¶ 9.

**8. Designation Of Deposition Transcripts.**

8.1 Portions of deposition transcripts containing CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY information may be designated as subject to this Protective Order either on the record during the deposition or by providing written notice within 30 days following receipt of the official transcripts of the deposition to the reporter and all counsel of record of the specific pages and lines that contain CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY information, in which case all counsel receiving such notice shall mark the copies or portions of the designated transcript in their possession or under their control as directed by the designating party.

8.2 All deposition transcripts not previously designated shall be deemed to be, and shall be treated as, HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY for a period of 35 days after receipt of the official transcript of the deposition, and the transcript shall not be disclosed during such time by a non-designating party to persons other than those persons named or approved according to ¶ 4.1(b)-(f).

8.3 The designating party shall have the right to exclude from portions of a deposition, before the taking of testimony which the designating party designates HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY and subject to this Protective



Order, all persons other than those persons previously qualified to receive such information pursuant to ¶ 4.1(b)-(f).

**9. Designation Of Hearing Testimony Or Argument.**

With respect to testimony elicited during hearings and other proceedings, whenever counsel for any party deems that any question or line of questioning calls for the disclosure of CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY information, counsel may designate on the record prior to such disclosure that the disclosure is subject to confidentiality restrictions. Whenever matter designated CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY is to be discussed in a hearing or other proceeding, any party claiming such confidentiality may ask the Court to have excluded from the hearing or other proceeding any person who is not entitled under this Order to receive information so designated.

**10. Disclosure To Author Or Recipient.**

Notwithstanding any other provisions of this Order, nothing herein shall prohibit counsel or a party from disclosing a document containing information designated CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY to any person who appears from the face of the document to have drafted, prepared, executed, or received the document, or any person who is reasonably likely to have had prior legal access to the document or the information contained therein.

**11. Designation Of Documents Under Seal.**

Any information designated CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY, if filed with the Court, shall be filed under seal pursuant to the procedures set forth in the Court’s rules and shall be made available only to the



Court and to persons authorized by the terms of this Protective Order. The party filing any paper which reflects, contains or includes any CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY information subject to this Protective Order shall file such paper in a sealed envelope, or other appropriately sealed container, which indicates the title of the action, the party filing the materials, the nature of the materials filed, the appropriate legend (see ¶¶ 2.1, 2.2), and a statement substantially in the following form:

**This envelope contains documents subject to a Protective Order of the Court. It should be opened only by the Court. Its contents should not be disclosed, revealed or made public except by Order of the Court or written agreement of the parties.**

**12. Confidentiality Of Party’s Own Documents.**

Nothing herein shall affect the right of the designating party to disclose to its officers, directors, employees, attorneys, consultants or experts, or to any other person, its own information. Such disclosure shall not waive the protections of this Protective Order and shall not entitle other parties or their attorneys to disclose such information in violation of it, unless by such disclosure of the designating party the information becomes public knowledge. Similarly, the Protective Order shall not preclude a party from showing its own information to its officers, directors, employees, attorneys, consultants or experts, or to any other person, which information has been filed under seal by the opposing party.

**13. Other Protections.**

13.1 No person shall use any CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY information, or information derived therefrom, for purposes other than the prosecution or defense of this action, including, without limitation, for purposes of preparing, filing or prosecuting any patent application, continuation or divisional patent application, reissue patent application or request for re-examination.

13.2 Any party may mark any document or thing containing CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY information as an exhibit to a deposition, hearing or other proceeding and examined, provided the witness is qualified under the terms of this Protective Order to have access to such designated material.

**14. Challenge To Confidentiality.**

14.1 This Protective Order shall not preclude any party from seeking and obtaining, on an appropriate showing, such additional protection with respect to the confidentiality of documents or other discovery materials as that party may consider appropriate. Nor shall any party be precluded from (a) claiming that any matter designated hereunder is not entitled to the protections of this Protective Order, (b) applying to the Court for an Order permitting the disclosure or use of information or documents otherwise prohibited by this Protective Order, or (c) applying for a further Order modifying this Protective Order in any respect. No party shall be obligated to challenge the propriety of any designation, and failure to do so shall not preclude a subsequent challenge to the propriety of such designation.

14.2 On any challenge to the designation of any information, the burden of proof shall lie with the producing party to establish that the information is, in fact, CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY information. If a party seeks declassification or removal of particular items from this designation on the ground that such designation is not necessary to protect the interests of the designating party, the following procedure shall be utilized:

(a) The party seeking such declassification or removal shall give counsel of record for the other party written notice thereof by facsimile, with confirmation by mail or by

personal delivery, specifying the designated information as to which such removal is sought and the reasons for the request; and

(b) If, after conferring, the parties cannot reach agreement concerning the matter within seven (7) business days after the delivery and receipt of the notice, then the party requesting the declassification or removal of particular items may challenge the designation by motion or at a regularly scheduled discovery conference.

**15. Inadvertent Failure to Designate and/or Inadvertent Disclosure.**

A producing party or non-party that inadvertently fails to designate an item pursuant to this Protective Order at the time of production may thereafter make a designation pursuant to this Protective Order by serving notice thereof in writing, accompanied by substitute copies of each item, appropriately designated. All copies of the misdesignated documents shall be promptly destroyed or returned to the producing party, and any memoranda or work product derived therefrom shall be promptly destroyed.

**16. Inadvertent Production or Disclosure of Privileged Materials.**

16.1 The inadvertent production or disclosure of any document or thing otherwise protected by the attorney-client privilege or work product immunity shall not operate as a waiver of any such privilege or immunity if, after learning of the inadvertent production or disclosure, the party who made the inadvertent production or disclosure sends to each receiving party a written request for return of the inadvertently produced or disclosed document or thing. Within ten (10) days of receiving such a request, the receiving party shall return to the producing party all such documents and things identified by the producing party as being privileged or work-product and as having been inadvertently produced and shall not utilize the information contained in such documents or things for any purpose.

(a) If the receiving party wishes to contest that any such document or thing was inadvertently produced or is protected by the attorney-client privilege or by work-product immunity, the receiving party shall so notify the producing party in writing when the document or thing is returned to the producing party.

(b) Within ten (10) days after receiving such notification, the producing party shall provide to the receiving party for each such document or thing a description of the basis for the claim of privilege or immunity.

(c) Within ten (10) days after receiving such description, the receiving party may file a motion to compel production of such documents and things, the protection of which is still disputed. If such a motion is filed, the producing party shall have the burden of proving that the documents and things in dispute are protected by the attorney-client privilege or by work-product immunity.

(d) With respect to documents and things subsequently generated by a receiving party, which documents and things contain information derived from such inadvertently produced documents and things, if the receiving party does not notify the producing party that the receiving party disputes the claims of attorney-client privilege or work-product immunity, the receiving party shall either destroy the derivative documents and things or redact from them all such derivative privilege or work-product information in a manner such that the derivative information cannot in any way be retrieved or reproduced.

**17. Prior or Public Knowledge.**

This Protective Order shall not apply to information that is or was available to the public prior to disclosure. The restrictions contained in this Protective Order shall not apply to information that is or was available to the public other than by an act or omission of the party to

whom such disclosure is made, or that is legitimately and independently acquired from a source not subject to this Protective Order.

**18. Limitation Of Protective Order.**

This Protective Order is not intended to address discovery objections to produce, answer, or respond on the grounds of attorney-client privilege or work product immunity, or to preclude either party from seeking further relief or protective orders from the Court as may be appropriate under the Federal Rules of Civil Procedure.

**19. Other Proceedings.**

By entering this order and limiting the disclosure of information in this case, the court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who may be subject to a subpoena, motion or court order in another case to disclose information that is designated by another party in this case as CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY in this case shall promptly notify that other party of the subpoena, motion or court order so that it may have an opportunity to appear and be heard on whether such information should be disclosed.

**20. Non-Party Material.**

The terms of this Protective Order, as well as the terms of any protective order that may be entered into between a discovering party and third party for the production of information to the discovering party, are applicable to CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY information provided by a non-party. Information provided by a non-party in connection with this action and designated CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY, pursuant to the terms of this Protective Order shall be protected by the remedies and relief provided by this Protective Order.

**21. Return or Destruction Of Designated Information.**

Within sixty (60) days following final termination of this action, unless otherwise agreed to in writing by an attorney of record for the designating party, each party shall assemble and return, or destroy and certify destruction of, all materials containing information designated CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY, including all copies, extracts and summaries thereof, to the party from whom the designated material was obtained, except that (a) any documents or copies which contain, constitute or reflect attorney's work product or attorney-client privilege communications, and (b) archive copies of pleadings, motion papers, deposition transcripts, correspondence, expert reports and written discovery responses may be retained by counsel, subject to a continuing obligation protect all such material pursuant to this order.

**22. Waiver Or Termination Of Order.**

No part of the restrictions imposed by this Protective Order may be waived or terminated, except by written stipulation executed by counsel of record for each designating party, or by an Order of the Court for good cause shown. The restrictions provided for herein shall not terminate upon the conclusion of this action, but shall continue until further Order of this Court.

**23. Modification Of Order; Prior Agreements.**

This Protective Order may be modified, and any matter related to it may be resolved, by written stipulation of the parties without further Order of the Court. This Protective Order supersedes any agreements between the parties regarding the confidentiality of particular information entered into before the date of this Protective Order.

**24. Section Captions.**

The title captions for each section of this Protective Order are for convenience only and are not intended to affect or alter the text of the sections or the substance of the Order.

**25. Days.**

All references to “days” in this Order shall be construed as calendar days, unless otherwise specifically indicated.

/s/ Anne Shea Gaza

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Dated: December 19, 2006

/s/ Richard D. Kirk

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*Attorneys for Defendant Teva  
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Dated: December 19, 2006



**IT IS SO ORDERED:**

Dated: \_\_\_\_\_

\_\_\_\_\_  
UNITED STATES DISTRICT JUDGE

**EXHIBIT A**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE AG, ALCON, INC.	)	
and ALCON MANUFACTURING, LTD.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No. 06-234 (SLR)
	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Defendant.	)	
	)	
_____	)	

**DECLARATION AND CONFIDENTIALITY UNDERTAKING**

I certify that I have received and carefully read the Stipulated Protective Order in this action and that I fully understand the terms of the Order. I recognize that I am bound by the terms of that Order, and I agree to comply with those terms. I hereby consent to the personal jurisdiction of the United States District Court, District of Delaware, for any proceedings involving the enforcement of that Order. I declare under penalty of perjury under the laws of the United States of America this Declaration and Confidentiality Undertaking is true and correct.

EXECUTED this \_\_\_\_\_ day of \_\_\_\_\_, \_\_\_\_\_.

\_\_\_\_\_  
Name

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Present Employer or Other Business Affiliation

\_\_\_\_\_  
Business Address